No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,
v.
MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION AND BRIEF OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS, INC. IN SUPPORT OF THE PETITIONER

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September 11, 1989

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MOTION OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS, INC. IN SUPPORT OF THE PETITIONER

Intellectual Property Owners, Inc. ("IPO") moves this court for leave to file the accompanying brief *amicus curiae* in support of the petition for certiorari. IPO has been unable to obtain the consent of the respondent pursuant to rule 36.1.[1]

IPO is a broadly based association with members in nearly all major industries. IPO's members manufacture

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[1] Counsel for respondent advised that respondent would not give its consent without an opportunity to review the proposed brief *amicus curiae*. IPO was unable to follow such a procedure within the time permitted by the rules of this Court for filing the brief.

several other types of products that could be affected by the decision of the Court of Appeals by the Federal Circuit besides the medical devices that are in dispute between the petitioner and the respondent. The Court of Appeals decision may affect patent rights in the areas of food additives, color additives, agricultural chemicals, and other nondrug products that are subject to regulation by the federal government or that may be subject to government regulation in the future.

IPO believes the information and views presented in its proposed brief would be useful to the Court as a supplement to the petition for certiorari. IPO's proposed brief emphasizes the broad national impact of this case and its potential impact on several industries. IPO's proposed brief presents facts relating to the intent of Congress in modifying the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984) that go beyond the facts presented in the petition for certiorari filed by Eli Lilly and Company.

IPO believes its proposed brief will assist the Court in understanding why this case may affect the international competitiveness of U.S. industry.

Respectfully submitted,

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QUESTION PRESENTED

Amicus curiae, Intellectual Property Owners, Inc. ("IPO"), adopts the question presented by petitioner Eli Lilly and Company, which is enclosed in quotation marks below, *except* that IPO would replace "FDA-regulated" in the last sentence below with "federally regulated" because IPO believes the Court of Appeals may have expanded the patent infringement exemption even beyond FDA-regulated products:

"35 U.S.C. § 271(e)(1) provides that 'it shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products*' (emphasis added).

"The question presented is:

"Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. § 271(e)(1) beyond 'drugs' and 'veterinary biological products' to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?"

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iv
INTEREST OF THE AMICUS CURIAE	1
ARGUMENT	2
I. AN IMPORTANT FEDERAL STATUTORY ISSUE SUBSTANTIALLY AFFECTING PATENT RIGHTS IS BEFORE THIS COURT	2
II. CERTIORARI IS NECESSARY TO REVIEW THE ANALYSIS BY THE COURT OF APPEALS BECAUSE OF THE BROAD IMPACT ON THE PATENT SYSTEM AND SEVERAL INDUSTRIES	3
CONCLUSION	7
APPENDIX	
Members of Board of Directors of Intellectual Property Owners, Inc.	1a

TABLE OF AUTHORITIES

CASES	Page
Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984)	4, 5
Fedorenko v. United States, 449 U.S. 490 (1981)	6
Hobbs v. McLean, 117 U.S. 567 (1886)	6
STATUTES	
35 U.S.C. § 271(a)	4, 5
35 U.S.C. § 271(e)(1)	*passim*
LEGISLATIVE MATERIALS	
H.R. 5529, 98th Cong., 2d Sess. (1984)	5
S. 1516, 100th Cong., 1st Sess. (1987)	5
Pub. L. No. 100-670 (1988)	6

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BRIEF OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS, INC. IN SUPPORT OF THE PETITIONER

INTEREST OF THE AMICUS CURIAE

Intellectual Property Owners, Inc. ("IPO") files this *amicus curiae* brief in support of the petition of Eli Lilly and Company for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered on March 29, 1989.

IPO was founded in 1972 by a group of individuals who were concerned about the lack of understanding of intellectual property rights in the United States. Members include nearly one hundred large and medium size companies and some smaller businesses and independent inventors who own patents and other intellectual property

rights. Members of IPO's Board of Directors are listed in the appendix to this brief. IPO is a nonprofit association exempt from federal income tax under Internal Revenue Code § 501(c)(6).

IPO conducts a government relations program in Washington, D.C. IPO supports legislation to strengthen protection available under the U.S. patent, trademark, copyright, and trade secret laws. Enactment of such legislation helps IPO's members and strengthens incentives for innovation and investment in the United States, improving the country's industrial competitiveness.

The Court of Appeals decision may erode patent rights not only in the area of medical devices, but also in the areas of food additives, color additives, agricultural chemicals, and other nondrug products that are subject to regulation by the federal government or may be subject to federal regulation in the future. This may weaken U.S. patent protection for IPO members, contrary to IPO's commitment to advocating strong rights in patents. IPO seeks to safeguard the full measure of the patent system that gives vital incentives for technological innovation, creativity and business investment.

ARGUMENT

I. AN IMPORTANT FEDERAL STATUTORY ISSUE SUBSTANTIALLY AFFECTING PATENT RIGHTS IS BEFORE THIS COURT

The possible ramifications of the Court of Appeals' decision are widespread. For the first time, otherwise-infringing competitors of the patent holder will be able to make, use, and sell patented medical devices during clinical trials before a patent expires. Otherwise-infringing competitors of the patent holder in the food and color additive industries, the agricultural chemical industry, and other industries also may be able to make, use, and sell patented inventions to obtain federal regulatory approval before the patent expires. This outcome may offer copiers a competitive advantage even though they did not undertake the substantial risk and expense in inventing and then establishing the commercial value of the inventions.[1]

In effect, the Court of Appeals decision may discourage that which the patent laws are intended to encourage—innovation, technological development, and investment in high-risk ventures. The decision may encourage copying instead, and weaken U.S. patent protection for nondrug, federally-regulated products.

II. CERTIORARI IS NECESSARY TO REVIEW THE ANALYSIS BY THE COURT OF APPEALS BECAUSE OF THE BROAD IMPACT ON THE PATENT SYSTEM AND SEVERAL INDUSTRIES

The Court of Appeals concluded that "ambiguous language" in the statute and "ambiguous statements in the legislative history" support inclusion of at least medical devices, food additives and color additives within the infringement exemption of 35 U.S.C. § 271(e)(1). *See* Pet. App. 5a.[2] The Court of Appeals apparently rejected or failed to consider several grounds relied upon by the District Court for limiting § 271(e)(1) to its plain language, which says the infringement exemption covers drugs and certain veterinary biological products.

The opinion by Circuit Judge Newman dissenting from the denial of a rehearing *en banc* (Pet. App. 10a) high-

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[1] There are reasons for distinguishing between drugs and nondrug, FDA-regulated products. Lilly's petition for certiorari sets forth the reasons, and they will not be repeated here. *See* Petition for Writ of Certiorari, pp. 14-18. As explained in this brief, IPO believes the Court of Appeals decision may also have ramifications for products regulated by agencies other than FDA.

[2] "Pet. App. 5a" refers to page 5a of petitioner's appendix. IPO will refer to petitioner's appendix on other occasions using the same citation form.

lights the incomplete nature of the analysis by the Court of Appeals. Judge Newman summarized the District Court opinion as follows:

> The district court had limited the statute to its plain terms, on the multiple grounds of the clear statutory language; the definition in the Food, Drug, and Cosmetic (FFDC) Act of "drugs" as excluding "devices or their component parts or accessories"; the absence of indication in § 271(e)(1) that "drugs" was intended to be interpreted contrary to the FFDC, which Act is referred to in § 271(e)(1); the distinct procedures set forth in the FFDC for drugs and devices; the clarity with which Congress specified the inclusion of medical devices when such was intended; and the legislative history that refers solely to drugs.

Pet. App. 11a.

The opinion by the Court of Appeals did not analyze the arguments considered by the District Court. Instead, the Court of Appeals adopted an extraordinary interpretation of how Congress, when it enacted § 271(e)(1), intended to alter the impact of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). According to the Court of Appeals, Congress intended "to set aside the *Roche* interpretation of § 271(a) in all of its ramifications" and allow a party to "make, use or sell *any type* of 'patented invention'" (Pet. App. 7a, emphasis in the original), provided the patented invention was used for the purpose of developing information to submit to a federal regulatory agency. IPO agrees with the petitioner that this interpretation is clearly in error. Petition for writ of certiorari, p. 13.

In *Roche*, the Federal Circuit interpreted § 271(a) as providing that it is infringing activity for a party to make, use or sell any patented invention for the purposes of developing information to submit to a federal regulatory agency. Congress in 1984 overruled *Roche* only with

respect to "drugs", whatever it meant by the term "drugs". Congress certainly did not intend to overrule the *Roche* interpretation of § 271(a) with respect to all patented inventions.

The 1984 version of § 271(e)(1) stated explicitly that it did not extend to an "animal drug or veterinary biological product". Moreover, when § 271(e)(1) was enacted Congress also had before it somewhat similar proposals affecting patent rights in agricultural chemicals regulated by the Environmental Protection Agency.[3] Apparently neither petitioner nor respondent believes Congress overruled the *Roche* interpretation of § 271(a) as it affects agricultural chemicals regulated by EPA. *See* petition for writ of certiorari, n.12. The petitioner presents the question as whether the Court of Appeals has expanded the patent infringement exemption to all FDA-regulated products.

IPO notes, however, that the Court of Appeals opinion, if read literally, would extend the reach of § 271(e)(1) even beyond FDA-regulated products, to agricultural chemicals and all other types of patented inventions regulated by *any* federal agency. The language in § 271(e)(1) does not limit the section to FDA-regulated, patented inventions. It covers ". . . uses reasonably related to the development and submission of information under *a Federal law* which regulates the manufacture, use, or sale of drugs or veterinary biological products" (emphasis added).

Most recently, the 1988 amendment to § 271(e)(1), which extended coverage to certain veterinary biological

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[3] *E.g.*, H.R. 5529, 98th Cong., 2d Sess. Congress subsequently has considered several other bills affecting patent rights in agricultural chemicals. Some of these bills have proposed to amend § 271(e) to refer specifically to agricultural chemicals. *E.g.*, S. 1516, 100th Cong., 1st Sess., § 2402, p. 167 (amendment to 35 U.S.C. § 271(e) covering pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act).

products, explicitly excluded biotechnology-related animal drugs and veterinary biological products, making clear again that the section does not cover all patented inventions.[4]

The Court of Appeals was mistaken in believing § 271 (e)(1) covers all types of patented inventions. This erroneous belief was the foundation for the court's entire opinion. As pointed out by Judge Newman, the Court of Appeals was legislating. Judge Newman observed that Congress, not the court, is empowered to legislate in matters affecting patent rights. (Newman dissent, reproduced at Pet. App. 13a, citing *Fedorenko v. United States*, 449 U.S. 490, 514 n.35 (1981) and *Hobbs v. McLean*, 117 U.S. 567 (1886)).

[4] The 1988 amendment of § 271(e)(1), expanding the section to cover certain veterinary biological products, includes subject matter regulated by the Secretary of Agriculture under the Virus-Serum-Toxin Act. *See* Pub. L. No. 100-670, Title II, "Patent Terms". Thus, § 271(e)(1) covers some subject matter not regulated by FDA.

CONCLUSION

The decision of the Court of Appeals could well have a negative impact on patent protection for innovators of medical devices, food additives, color additives, agricultural chemicals, and any other types of inventions that are regulated by the federal government or that might be regulated in the future. A grant of certiorari is respectfully requested to review the analysis of § 271(e)(1) by the Court of Appeals on this vital issue of national importance.

Respectfully submitted,

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